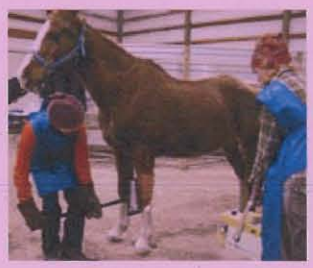
~~Controlled Copy 1~~

Quality Manual
Version 5.0
Effective Date: May 31, 2013


QUALITY MANUAL

State of Alaska

Environmental Health Laboratory
5251 Dr. Martin Luther King Jr. Avenue
Anchorage, AK 99507

Patryce D. McKinney
Chief, Environmental Health Laboratory

Table of Contents

Preface and Introduction

This Quality Manual is intended to guide the Alaska State Environmental Laboratory (EHL) towards the fulfillment of ISO 17025:2005. Red-colored text (gray in black-and-white printouts) indicates known gaps where EHL operations do not yet comply with the ISO 17025:2005 Standard. However, the text is still included in this Quality Manual to function as a roadmap towards ISO certification.

This Quality Manual was prepared with the guidance provided by NCCLS documents "*A Quality System Model for Health Care; Approved Guideline – Second Edition*" (document HS1-A2) and "*Application of a Quality Management System Model for Laboratory Services; Approved Guideline – Third Edition*" (document GP26-A3).

The Quality Manual is a compilation of twelve individual quality policies known as the Quality System Essentials (QSEs). The Quality System Essential (QSE) Policies describe the quality management system (QMS) for the State of Alaska, Environmental Health Laboratory (EHL). The purpose of the QSE Policies and QMS are to describe and document our quality management system, to define the authorities and responsibilities of the laboratory personnel, to set policy regarding activities pertaining to quality management, and to provide general procedures for all activities relating to the day-to-day operation of the laboratory.

The QSE Policies apply to all EHL employees and to all laboratory activities.

Approval for Implementation

Shera Hickman (Author)
Laboratory Quality Systems Manager

5/30/2013
Date

Patryce D. McKinney
Chief of Laboratory Services.

5-30-13
Date

QSE Policy: Organization

Quality Policy

The Alaska State Environmental Health Laboratory (EHL) provides environmental testing within the scope of its mission and in compliance with all applicable regulations and requirements. EHL, with the support of the Director of the Division of Environmental Health, is committed to good laboratory practices, to the quality of its testing activities, to providing good customer service to its clients, and to the continuing improvement of all of these operations. The Quality Management System (QMS), based upon the ISO 17025:2005 Standard, is the core and the foundation from which EHL operates, and is essential to its mission.

All EHL personnel must familiarize themselves with the QMS documentation, including this Quality Manual and supporting documents. Each person must implement the QMS policies and procedures as they perform the duties and responsibilities of their position, and seek to continually improve the service provided by EHL.

Our Laboratory

The State of Alaska Department of Environmental Conservation (DEC), Division of Environmental Health (EH), operates a single, permanent laboratory facility located at the following address:

State of Alaska
Department of Environmental Conservation
Division of Environmental Health
Alaska State Environmental Health Laboratory
5251 Dr. Martin Luther King Jr. Avenue
Anchorage, AK 99507

The EHL operates as a program within the Division of Environmental Health (EH), which is a division within the State of Alaska, Department of Environmental Conservation (DEC).

Mission

EHL's mission is to provide analytical and technical information in support of state and national environmental health programs. Such programs include but are not limited to those which survey and respond to emergencies involving: food products (shellfish, food, dairy products, etc.), water, sediments, animal tissues, and other miscellaneous products and materials.

The EHL also certifies commercial and municipal laboratories to conduct analyses of drinking water in support of the State of Alaska Drinking Water Program, approves commercial laboratories to conduct analyses of soils and water in support

of the State of Alaska Contaminated Sites Program, and approves milk products in support of the Dairy Program.

Compliance

EHL carries out its testing activities to meet the requirements of applicable regulations and standards and to satisfy the needs of its clients.

The laboratory testing programs are conducted in compliance with the requirements of various agencies, including, but not limited to:

- U.S. Department of Agriculture (USDA)
  - Animal and Plant Health Inspection Service (APHIS)
- U.S. Environmental Protection Agency (USEPA)
- U.S. Food and Drug Administration (FDA)
  - National Shellfish Sanitation Program (NSSP)
  - Center for Food Safety and Applied Nutrition (CFSAN)
- National Oceanic and Atmospheric Administration (NOAA)
- Occupational Safety and Health Administration (OSHA)
- U.S. Department of Transportation (DOT)

Quality Management System

EHL has established and maintains a documented Quality Management System (QMS) that includes the quality manual, individual Quality System Essentials (QSE) Policies, quality processes (QP), technical procedures (SOP), administrative procedures, work instructions (WI), and records specified in the individual documents.

The Laboratory's QMS covers work carried out in the laboratory's permanent facility.

EH laboratory's quality management system policies and objectives are defined in the Quality Manual. The Quality Manual consists of the twelve QSE Policies. The twelve QSE Policies are:

1. Organization
2. Customer Service
3. Facilities and Safety
4. Personnel
5. Equipment
6. Purchasing and Inventory
7. Process Control
8. Documents and Records
9. Information Management
10. Occurrence Management
11. Assessments
12. Process Improvement

The Quality Manual references supporting procedures where appropriate.

The structure of the QMS documentation is based on a tiered hierarchy as follows:

- **Level A – Quality Manual.** Includes QSE Policies and supporting documents. Describes the QMS in accordance with the stated quality policy and objectives and applicable standards.
- **Level B – Quality Processes.** Describes the activities of individual functional units needed to implement the quality system elements.
- **Level C – Technical and Administrative Procedures, and Other Quality Documents.** Includes Work Instructions, forms, references, product inserts, organizational charts, master lists, external documents (such as consensus and standard methods), etc.
- **Level D – Records.** Includes final reports, analytical data, bench sheets, chain-of-custody, training records, audit records, etc.

All laboratory personnel are responsible for following the policies and procedures documented in the QMS.

Change Management

The Laboratory Chief ensures the integrity of the management system is maintained when changes to the management system are planned and implemented.

Conflicts of Interest

Under no circumstances are any employees of EHL to participate in any activities that might adversely affect the integrity of their work. Conflicts of interest by EHL staff are governed by Alaska Statute (AS) 39.52, the Executive Branch Code of Ethics 9 AAC 52, and described in QP-02 Code of Ethics.

EHL has procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity. EHL employees are kept free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.

Reporting and Responsibilities

EHL has managerial and technical personnel who, irrespective of other responsibilities, have the authority (empowerment to require thought or behavior) and resources (facility, personnel, materials, know-how, equipment) needed to carry out their duties; including the implementation (training and daily operations) of the QMS; maintenance (audits, review); improvement (management review) of the QMS; identification of the occurrence of departures from the QMS; and initiation of actions to prevent or minimize such departures.

The occurrence of an employee title assumes that "or designee" follows for all Quality System documents, unless otherwise stated.

The titles of EH laboratory positions and their respective reporting relationships and responsibilities are presented in Figure 2, including appointed deputies for key managerial personnel.

The EHL organization chart (DEC Policy and Procedures Manual 01.01.302) lists position control numbers (PCN) for each EHL employee. Position descriptions are controlled external to the EHL in the Online Position Description (OPD) system and filed by PCN.

As shown in the organization chart, quality management, technical operations, and support services all report to the Laboratory Chief. Administrative support reports to the Division Director's Office.

Management Review

EHL management staff periodically conducts a review of QMS and testing activities to ensure their continuing suitability and effectiveness and to introduce necessary changes or improvements. The QMS documents, quality objectives, audit results, proficiency testing sample results, performance criteria, corrective actions, preventive actions, and improvements over the previous management review are evaluated. Findings from management reviews are recorded, actions are taken, and followup is recorded.

Supporting Documents

Quality Procedure: QP-02: Code of Ethics
Quality Procedure: QP-21: Reporting Test Results
Quality Procedure: QP-22: Management Review
DEC Policy and Procedures Manual 01.01.302: EHL Organization Chart

Figures

Figure 1: QSEs in EHL Quality Manual vs. ISO 17025:2005
Figure 2: EHL Reporting and Responsibilities
Figure 3: EHL Client Relationship Chart

Figure 1. QSES in EHL Quality Manual vs. ISO 17025:2005

QSEs	ISO 17025:2005 clause
Organization	• 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5 (a-b, d-j) • 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.2.7 • 4.15.1, 4.15.2
Customer Service	4.4.1, 4.7, 4.8, 4.1, 4.2
Facilities and Safety	5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.5
Personnel	4.1.5 (k), 4.2.1, 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5
Equipment	• 5.4.7.2(c) • 5.5.1, 5.5.2, 5.5.3, 5.5.4, 5.5.5, 5.5.6, 5.5.7, 5.5.8, 5.5.9, 5.5.10, 5.5.11, 5.5.12 • 5.6.1, 5.6.2.2, 5.6.3.1, 5.6.3.2, 5.6.3.4
Purchasing & Inventory	• 4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.4.5, 4.5.1 • 4.5.2, 4.5.3, 4.5.4, 4.6.1, 4.6.2, 4.6.3 • 4.6.4
Process Control	• 5.1.1, 5.1.2 • 5.4.1, 5.4.2, 5.4.3, 5.4.4, 5.4.5, 5.4.6, 5.4.7.1, 5.4.7.2(a) • 5.6.2.2 • 5.6.3 • 5.7 • 5.8 • 5.9 • 5.10.1, 5.10.2, 5.10.3, 5.10.4, 5.10.5, 5.10.6, 5.10.8, 5.10.9
Documents and Records	• 4.3.1, 4.3.2, 4.3.3 • 4.1.5, 4.2.1, 4.13, 5.1, 5.4.1 • 5.10.9
Information Management	• 4.1.5(c), 4.13.1.4 • 5.4.7.2(b) • 5.10.7
Occurrence Management	• 4.8 • 4.9.1, 5.5.7
Assessments	• 4.1.6 • 4.14.1, 4.14.2, 4.14.3, 4.14.4
Process Improvement	• 4.9.2 • 4.10.1, 4.10.2, 4.10.3, 4.10.4 • 4.11.1, 4.11.2, 4.11.3, 4.11.4, 4.11.5, 4.12.1, 4.12.2

Figure 2. EHL Reporting Relationships and Responsibilities

Position	Supervisor and Responsibilities Summary
Director, Division of Environmental Health	• Reports to the Commissioner, Department of Environmental Conservation; • Provides overall guidance to the Laboratory Chief; and • Maintains the organizational chart for the Division of Environmental Health.
Chief, Environmental Health Laboratories (Chief of Laboratory Services, Laboratory Chief)	• Reports to the Director of Environmental Health; • Manages all laboratory activities and testing services; • Serves as Certification Authority for the Drinking Water Laboratory Certification Program; • Presents and discusses the laboratory Quality Policy Statement with all personnel; • Controls access to the building through issue of hard keys to staff and authorities; • Specifies the responsibility, authority and interrelationships of all EHL personnel, in compliance with ISO/IEC 17025; and • The Technical Managers and the Quality Manager serve as backups for this position on a rotating basis.
Laboratory Quality Systems Manager/ Safety Officer Environmental Health Laboratory (QSM)	• Reports to Laboratory Chief; • Manages internal laboratory accreditation and certification; • Ensures compliance with Federal and State regulations promulgated by FDA, USDA, EPA, and CDC; • Provides accurate data and information regarding quality; • Ensures compliance with the International Standard ISO/IEC 17025:2005; • Reviews, revises, updates, and controls the QSE Policies and Quality Manual; • Supervises quality section staff; • Serves as Risk Manager; • Provides training in QSE Policies to all laboratory staff; • Distributes and controls QMS documents; • Ensures that the workplace is maintained and operated in compliance with OSHA regulations; • Provides safety training to all staff; • Maintains appropriate records of safety training; • Maintains Safety and Hygiene Plan; • Leads Quality Committee and Safety Committee; • Assesses and assures conformance to the Quality Manual, Quality Processes, Technical Procedures, Administrative Procedures, and Work Instructions; and • Is represented by the Laboratory Chief when absent.

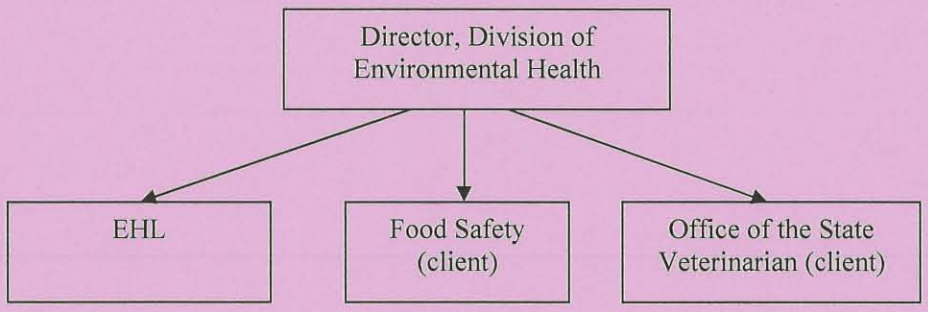
Figure 2. EHL Reporting and Responsibilities, cont'd.

Position	Supervisor and Responsibilities
Administrative Assistant, Environmental Health Laboratory	• Reports to the Division Administrative Officer; • Implements and maintains conformance to ISO/IEC 17025:2005, the Quality Manual, Quality Processes, Administrative Procedures, and Work Instructions; • Maintains the EHL organizational chart; • Procurement, personnel files, finance and budgeting; • Administrative support; and • May participate in Quality Committee and Safety Committee
Office Assistant, Environmental Health Laboratory	• Reports to the Administrative Assistant; • Customer Service, via telephone and in person; • Procurement; • Document management; • Administrative support; • May participate in Quality Committee and Safety Committee; and • Maintains conformance to ISO/IEC 17025:2005.
Laboratory Technical Managers, Environmental Health Laboratory	• Reports to the Laboratory Chief. • Implements and maintains conformance to ISO/IEC 17025:2005, the Quality Manual, Quality Processes, Technical Procedures, Administrative Procedures, and Work Instructions for their respective sections; • Supervises the laboratory staff of their respective sections; • Provides training in QSE Policies, procedures, work instruction and other quality documents; • Ensures compliance with the QMS; • Implements biological and chemical test procedures; • May participate in Quality Committee and Safety Committee; • Maintains high technical standards; • Maintains data integrity; • Implements corrective actions; and • Is represented by the delegated Microbiologist or Chemist of each section when absent.

Position	Supervisor and Responsibilities
Project Manager, Environmental Health Laboratory	• Reports to the Laboratory Chief. • Implements and maintains conformance to ISO/IEC 17025:2005, the Quality Manual, Quality Processes, Technical Procedures, Administrative Procedures, and Work Instructions; • Supervises assigned laboratory staff; • Provides training in QSE Policies, procedures, work instruction and other quality documents; • Report preparation and distribution; • Ensures compliance with the QMS; • Implements shipping, receiving, and client contact activities; • Implements biological and chemical test procedures as needed; • May participate in Quality Committee and Safety Committee; • Maintains high technical standards; • Maintains data integrity; • Implements corrective actions; and • Is represented by the Microbiologist supervised by this position when absent.
Microbiologists, Chemists, Technicians; Environmental Health Laboratory	• Reports to the Laboratory Technical Manager, Quality Manager, or Project Manager; • Perform biological and chemical testing procedures, and activities supporting testing procedures, in conformance with ISO/IEC 17025:2005, established methods, procedures, and client requirements; • Perform sample preparation procedures; • Review analytical results; • Prepare and review technical procedures; • Develop and validate new procedures as assigned; and • May participate in Quality Committee and Safety Committee.
Maintenance Specialist Environmental Health Laboratory	• Reports to the Laboratory Chief; • Maintains environmental, mechanical, electrical, and life safety systems, either directly or via outside contractors, in conformance with ISO/IEC 17025:2005, and applicable federal requirements; • Maintains physical grounds; • Arranges for facility modification; • Administers construction and maintenance contracts; and • May participate in Quality Committee and Safety Committee

Position	Supervisor and Responsibilities
Analyst/Programmer Environmental Health Laboratory	• Reports to the Laboratory Chief; • Administers the Laboratory Information Management System (LIMS); • Diagnoses database problems; • Develops new applications and queries; • Performs routine database backup and maintenance; • Provides desktop support; • Performs WAN/LAN administration; • May participate in Quality Committee and Safety Committee; • Controls access to the building through issue of electronic keys to staff and authorized contractors; and • Other associated Information Technology (IT) duties.
Quality Committee Environmental Health Laboratory	• Reports to the Laboratory Chief; • Chaired by Quality System Manager; • Consists of both supervisory and non-supervisory staff; • Reviews QMS documents; • Evaluates analytical and operational trends, such as control charts or performance measures; • Addresses non conformances; • Conducts internal audits; • Implements quality policies; • Makes recommendations for improvement; and • Meets Quarterly.
Safety Committee Environmental Health Laboratory	• Reports to the Laboratory Chief; • Chaired by Safety Officer, designee of the Laboratory Chief; • Consists of both supervisory and non-supervisory staff; • Reviews Safety Plan/Chemical Hygiene Plan; • Addresses concerns raised by staff; • Issues recommendations for improvement; and • Meets Quarterly.

Figure 3: EHL Client Relationship Chart



QSE Policy: Client Services

Policy

EHL cooperates with its customers to:

- Clarify work request issues pertaining to their request for services;
- Select methodologies that are capable of meeting the customers' requirements;
- Assure that EHL capabilities meet the customers' requirements; and
- Monitor the testing services that the laboratory performs.

The Quality Systems Manager (QSM) and Laboratory Managers are jointly responsible for the final approval of all new work performed by EHL, and for implementing new work processes. The QSM approves and documents any additions or changes to the quality system caused by accepting new work.

EHL maintains a documented procedure that addresses complaints from clients, State agencies, Federal agencies, and corporate organizations, as well as any outside complaints, and the actions required to resolve the complaint.

Contract Acceptance Review

For many sampling and analysis programs, testing design is site or program specific. EHL has the ability to provide both standard and customized laboratory service to our clients. To ensure project success, management staff perform a thorough review of technical and quality assurance requirements contained in work plans. Work plans comparable to Quality Assurance Project Plans (QAPPs) and Statements of Work (SOW) are reviewed for defined requirements and EHL's capability to meet those requirements before a project is accepted and the analytical work begins.

Any agreement or amendment to a work plan communicated to EHL verbally is confirmed with the client in writing, and becomes part of the permanent project record. Any discrepancy between the client's requirements and EHL's capability to meet those requirements is resolved in writing by the Laboratory Chief before acceptance of the work plan. Amendments, initiated by the client and/or EHL, are documented in writing for the benefit of both the client and EHL.

A thorough review of the services being requested is conducted before the laboratory performs additional work within its scope or to expand its scope of testing. The Laboratory Chief, with input from the Technical Managers and Quality Systems Manager (QSM), considers available resources and both current and pending workload prior to accepting new work.

For the laboratory to expand its scope of testing, the same considerations must be given, as well as evaluation of the feasibility of/and time frame for method

development and proficiency demonstration. The availability of and requirements for certification are considered. Laboratory management including the Laboratory Chief, Quality System Manager, and Section Managers consider all above factors.

A plan of implementation is developed for any new methods developed in the laboratory. This plan includes making provisions for acquiring necessary equipment, reagents, standards, analyst training, creation of SOPs, performing initial demonstration of capability and method detection limit studies, where applicable.

EHL treats the origination and review of contract amendments identically to contract origination. The Project Manager as appropriate communicates the specifics of approved amendments in an existing agreement to affected laboratory personnel as soon as practicable.

Clients are informed of any deviations from originally approved contracts.

Any differences between the work order request or chain of custody form and the contract are resolved before any work commences.

Project-Specific Quality Planning

Communication of contract or client specific technical and QC criteria is an essential activity for the success of any testing program. EHL assigns each client a single Project Manager (PM). The PM may be any member of the laboratory management team. It is the responsibility of the PM to ensure that project-specific technical and QC requirements are effectively communicated to the laboratory personnel before and during the project.

EHL establishes procedures to ensure that communication is inclusive and effective. These include project memoranda, meetings of project contacts, LIMS client checklists, QSM summaries and start-up meetings between the laboratory staff and the client. EHL strongly encourages our clients to visit the laboratory and hold formal or informal sessions with employees in order to effectively communicate client needs on an ongoing basis.

Subcontracting of Tests

The requirements for reviews of requests, tenders, and contracts are also applicable to work subcontracted by the laboratory.

EHL subcontracts testing services, when necessary. This may occur if the request for analytical services falls outside EHL scope of capability, capacity, or in the event of equipment malfunction where the equipment cannot be repaired within a suitable period. EHL informs the customer in writing if a sample or samples is to be subcontracted. If contractually required, approval is obtained from the client before subcontracting samples.

To demonstrate that the subcontractor is competent to perform the activities in question, EHL uses subcontractor laboratories that are accredited to the regulatory criteria applicable, including the current version of ISO 17025.

If the subcontract laboratory is not accredited to ISO/IEC 17025 where accreditation is required, then EHL either:

- documents the favorable review of the elements of the subcontractor's quality system, including but not limited to the subcontractor's:
  - quality manual
  - quality procedures
  - analytical procedures
  - proficiency test results and corrective actions
  - audit results and corrective actions; or
- audits the subcontractor's quality system against specific requirements that relate to the proposed subcontracted work; or.
- evaluates if the lab meets the standards of the appropriate regulatory agency for the specific project.

The subcontractor must rectify any non-conformity to EHL satisfaction before receiving a work assignment.

EHL assumes full responsibility for work subcontracted at its sole direction.

The QSM maintains a register of approved laboratory subcontractors and records evidence of the subcontractor's compliance with the requirements of the QMS.

Client Feedback

EHL seeks feedback from its clients. Listening to and documenting our client's feedback, both positive and negative, allows EHL to capture "client knowledge", and thus continually improve internal processes. The number and nature of feedback events is documented and communicated to management.

EHL believes that an effective client feedback handling process has important business and strategic value. Implementation of a fair and responsive client feedback system provides assurance to the data user that the lab will stand behind its data, service obligations, and products.

Client feedback is documented, communicated to management, and addressed promptly and thoroughly. Client feedback is documented by the employee receiving the feedback. The Laboratory Chief, Quality Systems Manager, Project Manager, and Section Managers as applicable are notified of all client feedback, and assist in resolving any complaints.

The number and nature of client feedback is documented and evaluated. The overall number of feedback received is tracked and the appropriateness of the response to

client feedback is assessed. Monitoring and addressing the overall level and nature of client feedback and the effectiveness of the solutions is part of the annual management review.

Complaints

The Quality Systems Manager (QSM) reviews all complaints. The procedure specifies the role and responsibilities of the QSM and other personnel, and the records that EHL maintains regarding the complaint and any necessary corrective actions taken.

A complaint is investigated, and an appropriate action is determined and taken. In cases where a client complaint indicates that an established policy or procedure was not followed, the Quality Systems Manager may conduct a special review to assist in resolving the issue. A written confirmation or letter is sent to the client outlining the issue and response, if warranted.

Client Visits

Visits to the laboratory by interested parties such as clients, auditors, contractors, etc., are coordinated through one of the following personnel: Laboratory Chief, Quality System Manager, Administrative Operations Manager, Project Manager, Maintenance Specialist, or Laboratory Technical Managers.

Staff members ensure that customers' proprietary information and data are protected during visits by any clients or customers.

Client Notification

The Project Manager notifies clients in writing and/or verbally of (a) delays or major deviations in the performance of tests, and (b) any work that was affected by deficiencies, audit findings, or nonconformances that may have affected the overall quality of a test result.

Records

EHL maintains records of client service activities, including:

- work requests;
- client feedback;
- pertinent discussions with management; and
- work that EHL subcontracts.

EHL informs clients of any deviations from the work request.

Supporting Documents

QP-01 Client Confidentiality
QP-06 Client Feedback
QP-17 In-House Validation of Methods
QP-21 Reporting Test Results
QP-23 Visitor Security

QSE Policy: Facilities and Safety

Policy

EHL performs its work operations in an environment with accommodations and facilities that ensure the quality of the results, and safety of its employees.

Accommodation and Environmental Conditions

Laboratory personnel document the required accommodation and environmental conditions specific to each test activity, including but not limited to energy sources, lighting and environmental conditions, to facilitate correct performance of the tests.

The Laboratory Technical Managers and staff are responsible for monitoring the laboratory environmental conditions.

The laboratory uses hygrometers and thermometers to measure humidity and temperature. Automated electronic systems control conditions and monitor for compliance with alarm limits. Any laboratory staff member may halt ongoing tests whenever environmental conditions jeopardize the result of the test activity.

The laboratory maintains adequate separation between areas in which there are incompatible activities to prevent the contamination of testing materials and results. The EHL laboratory floor layout appears in **Figure 1**. Tests are not undertaken at sites other than the permanent laboratory facility.

EHL maintains a secure, controlled environment for all laboratory activities and staff. Entrances to the interior of the facility are locked at all times. Security is provided by a combined system of electronic and "hard key" access for EHL employees and authorized contractors. Employees and authorized contractors gain access to the building through the use of personalized electronic key(s) which actuate electrically operated solenoids at the various entrances to the facility. Certain high security rooms in the laboratory, such as the Mechanical Room, Electrical Room, Telecom Room, and administrative offices require a hard key to gain access. All keys (electronic and hard keys) are issued and controlled by the Analyst/Programmer and the Administrative Assistant respectively. Customers, non-EHL State employees, members of the public, and/or other visitors cannot gain entry into the facility without explicit permission from a member of the EHL staff.

Laboratory employees maintain their work areas in a clean, orderly and organized manner. All individual work areas are maintained with minimal clutter, paperwork, and debris. Passageways are clear and free from obstructions and not used as storage areas for chemicals, carts, boxes, or miscellaneous debris. More specific housekeeping procedures are developed when necessary.

Health and Safety

Simple compliance with OSHA regulations is not sufficient to ensure the safety of employees. EHL fosters a culture that places the safety of all laboratory employees as the foremost priority. Laboratory employees, whether administrative or technical, are likely to come into contact with or work with samples of unknown origin, bio- or chemical terrorism agents, hazardous chemicals, pathogenic organisms, and mechanical hazards. A corporate culture that fosters constant attention to safety is essential to reducing the incidence of accidents.

All laboratory personnel are responsible for safety. Practices that endanger the health or safety of any member of the staff are halted until appropriate safety measures have been implemented. The laboratory incorporates engineering controls to ensure a safe environment exists to perform laboratory testing. Safety equipment is routinely inspected and tested to ensure proper functioning.

Technical Procedures, Administrative Procedures, and Work Instructions include a description of the safety hazards associated with each procedure.

Health and Safety Plan

Numerous chemical; biological; mechanical; electrical; blood-borne pathogenic; slip, trip and fall; and other hazards exist in the laboratory workplace. The Safety Officer and Safety Committee maintain a laboratory Health and Safety Plan to address the known hazards existing in the laboratory and the procedures employed to reduce the threats posed by these hazards. The Health and Safety Plan addresses the procedural controls, engineering controls, and policies relevant to the maintenance of a safe laboratory workplace for all employees.

The Safety Officer and Safety Committee review and update the Health and Safety Plan annually or as needed.

Chemical Hygiene Plan

In accordance with Occupational Safety and Health Administration (OSHA) laboratory standards, the Safety Officer and Safety Committee prepare and update a Chemical Hygiene Plan within the EHL Safety Plan that addresses the hazards associated with EHL operations.

Safety Training

The Laboratory Chief provides the Safety Officer with the necessary resources to provide all employees safety training as required by OSHA and the State of Alaska. Training requirements vary depending upon the duties of each employee. The EHL safety training program has two parts:

- General safety training for safety issues common to all laboratory staff; and
- Task-specific safety training, which is provided at the same time as training for the task.

The Safety Officer reviews the training, and the employee documents all training in the employee training file or electronic means.

Disaster Preparedness and Recovery

Disaster preparedness and recovery encompasses two major activities:

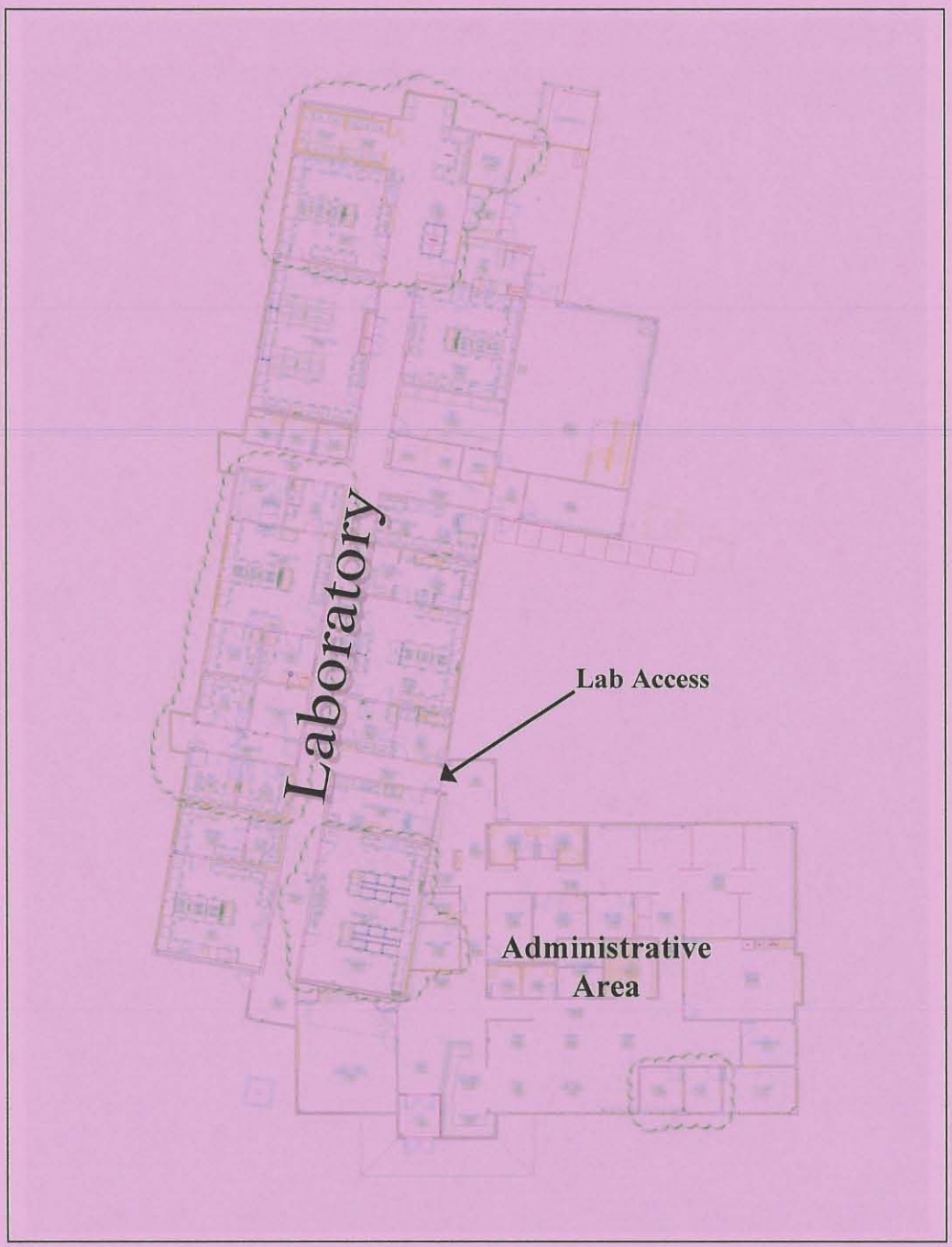
- EHL response to external disasters, either natural or man-made; and
- The inability of EHL to provide testing services to its clients, for whatever reason (loss of facilities, loss of computer support, etc.)

The EHL maintains appropriate procedures for responding to each type of disaster.

Supporting Documents

QP-07 Safety and Chemical Hygiene Plan
QP-28 Facilities
QP-27 Disaster Preparedness and Recovery

Figure 1: EHL Floor Layout



QSE Policy: Personnel

Policy

Only trained and qualified personnel authorized by laboratory management operate or maintain equipment, perform tests, evaluate results, and sign test reports. Training is performed by personnel who have documented qualifications and competence. Personnel undergoing training are under direct and immediate supervision by certified staff.

Job Qualifications and Descriptions

The policies and procedures for recruitment, evaluation, and hiring for all State of Alaska employees are governed by the State of Alaska Department of Administration and the Division of Personnel.

The State of Alaska Division of Personnel maintains Class Specifications and Position Descriptions. Class Specifications and Position Descriptions document the technical, educational, supervisory, management, and quality skills necessary for the job. Position Descriptions document the job accountabilities and responsibilities for each laboratory employee.

EHL selects staff based on the individual's ability to meet the criteria in both the Class Specifications and the Position Descriptions.

Individual Certification

Employees performing analytical testing may require certification from outside agencies such as the FDA, USDA, or EPA. The Laboratory Technical Managers ensure that all required certification requirements are met for individual analysts before they are authorized to perform testing of client samples. Documentation for these outside agency certifications is maintained in the employee's training file.

Technical management, at a minimum are familiar with methods and procedures, with the purpose of each test, and with the assessment of the test results. This knowledge allows them to provide adequate supervision of testing and calibration staff, including trainees.

Training

EHL technical management formulates training goals with respect to the education, training and skills of the lab personnel. The training program is relevant to the present and anticipated tasks of the lab.

EHL maintains a documented procedure that addresses identifying the training needs of EHL staff and the provision of training to the staff.

At a minimum, training includes the following elements:

- Review of the document(s), procedure(s) and/or work instruction(s) relevant to the task;

- Overview of the task with supervisory or other competent personnel. Various media may be used to present important concepts;
- For analytical testing or sample preparation, an Initial Demonstration of Capability is completed, with periodic participation in proficiency tests thereafter;
- For administrative or safety related training, a written test may be employed to reinforce important concepts and demonstrate competence; and
- Documentation of the training in the training records, including acknowledgement and approval signatures from trainee, supervisor, and Quality Assurance, as applicable.

Where contracted and additional technical and key support personnel are used, EHL ensures that such personnel are supervised, competent, and that they work in accordance with the lab's management system.

Initial Demonstration of Capability

To ensure individual competence, all laboratory personnel who perform testing successfully complete an Initial Demonstration of Capability (IDC) for each analytical method they perform. The IDC is performed after initial training. Batch number references to the results of the IDC are documented in the employee's training file. The IDC is evaluated, and approved in writing by the employees' direct supervisor and the QSM before the employee is authorized to perform analysis of client samples. The specific technical requirements for a successful IDC are method dependent and are detailed in Quality Procedures, Technical Procedures, and/or Work Instructions.

Training records

EHL maintains records that specify the authorizations given to personnel to perform tests and issue reports, and the educational and professional qualifications, training, skills and experience of laboratory staff.

Supporting Documents

Quality Procedure: QP-13 Personnel Qualifications and Training
Staff Class Specifications (maintained by the Department of Personnel)
Staff Position Descriptions (maintained by the Department of Personnel)

QSE Policy: Equipment

Policy

The EHL has and maintains the sampling, measuring, and test equipment necessary for the correct performance of its testing activities.

EHL owns all of the analytical equipment used by the laboratory, except that which has been purchased by a Federal grant. If EHL chooses to lease or borrow equipment, the equipment will meet the needs required by the methods employed and the QMS.

EHL maintains a documented procedure that addresses the control and maintenance of all laboratory equipment, including the software associated with the equipment. The procedure addresses the validation, safe handling, transport, storage, use and planned maintenance of measuring equipment, and the safeguarding of the equipment from unauthorized adjustments, contamination or deterioration.

Equipment Identification

State of Alaska asset tags are used to uniquely identify all major testing equipment. The Administrative Assistant as appropriate ensures that laboratory equipment receives an asset tag and is properly identified according to State of Alaska policy prior to use. The Administrative Assistant maintains a list of all EHL asset-tagged equipment, including major testing equipment, computer hardware and data processing equipment. The official DEC inventory asset master list is administered by the DEC Division of Administrative Services. The Administrative Assistant communicates list changes to DAS.

Smaller testing equipment, which do not have asset tags, are uniquely identified by their manufacturer and serial number. The master list of all calibrated equipment is maintained by the QSM.

Validation

All equipment placed into service in the laboratory undergoes a validation process before use for analysis of client samples. This ensures that all equipment used for testing is capable of achieving the specific performance specifications required for the tests concerned. Validation requirements vary depending on the type of equipment and the method. The specific requirements for equipment validation are detailed in the quality procedures, technical procedures, and/or work instructions.

Equipment is placed into service only after approval of the validation process by the Laboratory Technical Manager(s) and/or Quality Systems Manager (QSM). Documentation of all equipment validation and approval is kept in the calibration/maintenance log for that room or piece of equipment, as applicable.

Calibration

EHL maintains procedures that address the calibration of analytical equipment. Equipment types that require calibration include analytical balances, top loading

balances, thermometers, and pipettes, and any equipment having a significant effect on the uncertainty, accuracy or validity of the result of the test. Equipment that uses measuring functions must be calibrated, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result.

Equipment identified as requiring calibration has a tag, sticker, and/or an associated logbook that documents the inspection and calibration by a calibration authority. This includes the status of calibration and the calibration due date.

Certain classes of equipment, such as analytical balances, thermometers, etc., require periodic verification of calibration. Calibration verification is performed on a frequency defined by the appropriate quality procedure, technical procedure or work instruction. The results of calibration verification are documented.

Correction factors, where applicable, for calibrated equipment are documented, with the correction factor printed on a label attached to the equipment.

Other classes of analytical instrumentation such as pH meters, gas chromatographs, mass spectrometers, etc., require periodic standardization and verification. The requirements for standardization are summarized in the Standard Operating Procedures specific to the analytical method and instrument.

Equipment calibration is made in SI units. If SI unit measurement is not possible, then traceability is established via certified reference materials, the use of specified methods, and/or consensus standards. EHL participates in suitable programs of interlaboratory comparisons where possible.

When using external calibration services, traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these services include the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

Reference Standards

EHL uses some weights, thermometers, and other equipment as internal reference standards. Reference standards are periodically sent to an external calibration service, which meets the minimum requirements of the EHL Quality System. Their calibration is checked both before and after adjustment or repair by the calibration service. Reference standards are used solely for checking the calibration of other equipment. EHL has procedures for safe handling, transport, storage, and use of reference standards to prevent their contamination or deterioration.

Maintenance and Repair

EHL maintains all equipment according to the manufacturers' specifications as published in the manufacturers' manuals.

Installation and maintenance records for all equipment are maintained by Laboratory Technical Managers and staff. Routine and non-routine maintenance and repair of equipment is documented by EHL personnel in an instrument specific maintenance logbook located in the vicinity of the equipment. Laboratory personnel who perform routine and non-routine maintenance of analytical instrumentation document the date of the maintenance, nature of the problem, steps taken to resolve the problem, and the final outcome. Maintenance or repairs performed by outside vendors or service engineers are similarly documented by laboratory personnel.

Computer Systems

The EHL maintains its computer system hardware and software to ensure proper functioning and provides the appropriate environment and operating conditions necessary to maintain the integrity of testing data and related information.

Equipment Operation

EHL only allows trained and qualified personnel to operate analytical equipment. The Laboratory Technical Managers ensure that the necessary procedures and manuals are up-to-date and available for use by laboratory staff that operate the equipment.

EHL performs testing only at the permanent facility identified in Quality System Essentials Policy QSE-01. Test equipment is not shipped outside of the facility unless approved by the Laboratory Chief, or where shipment of equipment for repair or calibration is required. The laboratory follows manufacturers' recommendations for shipment of equipment for repairs or calibrations. When equipment does return from being repaired, the laboratory ensures the function and calibration status of the equipment are satisfactory before the equipment is returned to service. When equipment returns from being calibrated, its function is checked and the calibration certificate is approved before the equipment is returned to service.

EHL personnel remove equipment that does not operate as required, with expired calibration, has been subject to overloading or mishandling, or appears defective. The equipment is clearly identified with a laboratory "Out-of-Service" tag, and documented. Laboratory personnel remove the tag only after the equipment has been repaired and proper operation, function, and/or calibration status have been demonstrated.

Laboratory personnel evaluate sample data validity according to QSE-10 Occurrence Management, whenever equipment used in the analysis exhibits operation outside control limits, does not meet method requirements, or whenever equipment operation does not meet expectations. The evaluated sample sets are those included from the time of the deficiency to the time the system was in statistical control.

EHL safeguards against adjustments to test equipment (both hardware and software) by training staff in the proper operation of test equipment, controlling access to the laboratory, escorting visitors, and performing calibration checks and standardizations of test equipment before use.

Records

The laboratory maintains records for each item of equipment and for reference materials significant to the analyses performed by the laboratory. Records include the identity of the equipment and/or software; designated location or room number; serial numbers; installation documentation; validation results; instrument manuals; calibration results; acceptance criteria, due date (where applicable) for the next calibration; maintenance plan; maintenance carried out to date; and any damage, malfunction, or repair to the equipment.

Supporting Documents

Quality Procedure: QP-16 Equipment Control and Maintenance

QSE Policy: Procurement and Inventory

Policy

EHL maintains documented procedures governing the purchasing of laboratory services, supplies and equipment. The procedures address:

- Identifying testing requirements and communications;
- Ensuring that procured items meet testing requirements.

The Alaska Administrative Manual describes all statewide procurement requirements. The Administrative Assistant is responsible for all procurement policies and processes.

Contracts and Amendments

EHL treats the origination and review of contract amendments identically to contract origination. Contracts for service include Reimbursable Service Agreements (RSAs), Memorandums of Understanding (MOUs), Memorandums of Agreement (MOAs), standard agreements, and standard contracts.

Subcontracting of Tests

EHL subcontracts testing services, when necessary. This may occur if the request for analytical services falls outside EHL scope of capability, capacity, or in the event of equipment malfunction where the equipment cannot be repaired within a suitable period.

Regulatory, program, or client criteria are used to justify selected subcontract facilities according to Alaska State procurement rules. ISO 17025:2005 is used where required by the client or regulatory program.

Purchasing Services and Supplies

EHL maintains a documented procedure that addresses the selection, evaluation, and control of purchased products and services that affect the quality of the laboratory's tests.

All laboratory procurements are conducted in accordance with State of Alaska guidelines, procedures, and statutes.

The Managers are responsible for maintaining inventory control and management of supplies for their respective sections, and for maintaining sufficient supply inventory to ensure operations are not interrupted due to supply shortages.

EHL uses suppliers based on their ability to provide acceptable services and supplies to the laboratory. The procedure specifies the criteria for the selection, evaluation, and re-evaluation of suppliers. EHL maintains a list of approved suppliers.

Documents used to procure products and services clearly specify the type of product or service to be purchased, and clearly state the specified acceptability requirements, including requirements for personnel and QMS requirements. The purchaser reviews the accuracy of the purchase requirements before forwarding the request to the buyer.

Supporting Documents

Alaska Administrative Manual AAM 81. Procurement.
Quality Procedure: QP-05: Procurement

QSE Policy: Process Control

Policy

Due to uncertainty associated with the measurements performed in the laboratory, EHL considers several factors when developing test methods and procedures, when selecting and training laboratory personnel, and when selecting and calibrating laboratory equipment, among them:

- human factors,
- environmental conditions,
- equipment, test methods,
- traceability, and
- sample handling.

Test Methods

EHL uses methods and procedures for analyses and related activities within its responsibility including:

- sample handling,
- sample transport,
- pre-testing storage,
- sample preparation,
- sample analysis,
- estimation of measurement uncertainty,
- analysis of test data, and/or
- post-testing storage.

Methods used are consistent with client and regulatory requirements. Laboratory performance statements of accuracy and precision are developed during the in-house validation of all methods. A database of results is maintained to monitor the accuracy and precision of the methods.

The laboratory uses consensus and/or standard methods, when available, as a source of guidance for the analysis. Where feasible, the laboratory uses the most recent versions of consensus and/or standard methods. The laboratory may also use in-house developed methods or methods specified by the manufacturer of the equipment. The client is informed of the method chosen.

If a client requests a specific method to be used, EHL informs the client when the method proposed by the client is considered to be inappropriate or out of date. When the client does not specify the method to be used, EHL selects the appropriate method based on published regulatory requirements.

New Methods

The authority to implement a new method into the laboratory lies exclusively with the Laboratory Chief.

When new test methods are introduced, the Laboratory Chief, Laboratory Technical Manager(s), and QSM jointly develop an implementation plan for that test method's overall validation that contains requirements and objectives necessary to insure the method is fully valid, the staff fully trained, and resources are available to perform the test .

The introduction of test methods developed by EHL for its own use is a planned activity and is assigned to qualified personnel equipped with adequate resources. As development of EHL-developed methods progress, Plans (i.e. Procedures) are updated and there is effective communication amongst all personnel involved.

Method Validation

Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

All test methods performed in the laboratory, whether consensus/standard methods or laboratory-developed methods, are validated before use.

Client samples are not analyzed until:

- completion of the validation is documented,
- the validation is approved by the Laboratory Technical Manager(s) and Quality Systems Manager (QSM),
- analyst training documentation is completed, and
- The Standard Operating Procedure is approved.

The specific technical requirements for a successful method validation are dependent on the method. They are described within the documentation of each method validation.

The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results; detection limit; selectivity of the method; linearity; limit of repeatability and/or reproducibility; robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object; or comparability to the established method), as assessed for the intended use, shall be relevant to the client's needs.

Non-standard or Laboratory-Developed Methods

Methods used that are not consensus/standard methods are subject to agreement with the client and/or regulatory agency, and documented. The laboratory validates non-standard methods, laboratory-developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods. The laboratory maintains records of the results, procedure used for validation, and whether the method meets client and/or regulatory requirements.

Validation of non-standard methods includes the preparation of a validation plan, preparation of a technical procedure or work instruction, performance of the validation, determination of measurement uncertainty, and completion of training documentation for personnel performing the test(s). Additional requirements may be appropriate depending on the complexity of the method and the needs of the given application or field of application.

Records of method validation data for non-standard and/or laboratory-developed methods are maintained.

Measurement Uncertainty

A determination of measurement uncertainty is made for all analytical tests performed by the laboratory. All uncertainty components which are of importance in the given situation are taken into account using appropriate methods of analysis. The uncertainty associated with measurements conducted on samples is included in the final analytical report issued to the client.

Calculations

Calculations performed by commercially purchased analytical data systems, which are used under the conditions for which the system was designed, do not require external validation. The method validation serves as the validation for these types of systems. Internally developed software utilized for laboratory operations is fully validated before implementation. Calculations and data transfers are subject to appropriate checks in a systematic manner. Calculations applied by EHL employees or contractors and performed by spreadsheet macros, LIMS, databases, or any other automated means are validated prior to use. For simple spreadsheets and databases the validation may simply consist of repeating the calculation by hand and ensuring a hand calculation matches the automated calculation. More complex algorithms may require more extensive validation. Processes for automated uploading of analytical results to a LIMS are validated to ensure results are properly entered. The results of these validations are documented.

For some tests, the laboratory uses computers to capture data as they are generated by the analytical instruments. In these cases, the analytical microprocessor performs data reduction.

Data in various formats are entered into the Laboratory Information Management System (LIMS), either manually or by automatic upload. The LIMS may perform additional data reduction steps prior to reporting.

Measurement Traceability

The laboratory's calibration certificates indicate the traceability to national standards of measurement, when available. They also provide the measurement results and associated uncertainty of measurement, and a statement of conformance with an identified metrological specification, where available. These certificates are traceable records.

EHL uses independent reference materials and reference standards of measurement (i.e. equipment), in which their single purpose is to verify calibration. Laboratory personnel document the receipt and use of calibration materials and check samples.

EHL uses a third-party metrologist who can provide traceability to the National Institute for Standards and Technology to calibrate laboratory reference standards of measurement, analytical balances, top loading balances, and masses.

Reference materials, reagents, analytical standards, pre-prepared media, and other materials utilized for performing standardizations or analyses have a certificate from the manufacturer testifying to composition and purity. The certificate is retained by EHL to document the traceability of starting materials used for analysis.

Sampling

Proper sampling protocols, appropriate sample preservation, complete chain-of-custody, and industry compliant shipping procedures are a critical element of overall data quality. For industry samples, these processes are outside the scope of EHL operations or direct control; however, EHL personnel recognize the need to provide technical and administrative support to the organizations and individuals who perform sampling and shipping of samples to EHL.

EHL provides, when appropriate, certified pre-cleaned sample bottles, containers, sterile containers, shipping materials, and/or sample submission forms to clients. Sample bottles and containers contain the appropriate chemical preservatives for the analytical method at hand.

For internal QA testing, EHL follows QP-20 Quality Control sampling protocol. The sampling procedures include the selection of sampling sites, withdrawal and preparation of a sample, pertinent equipment calibrations, and what and where relevant data is collected and recorded.

Where the client requires deviations, additions or exclusions from the documented sampling procedure, these are recorded in detail with the appropriate sampling data and are included in all documents containing test results, and are communicated to the appropriate personnel.

Laboratory Submission Manual

The laboratory maintains a Laboratory Submission Manual for distribution to clients, samplers, or any other agency desiring information regarding the laboratory. The Laboratory Submission Manual serves as a guidance document, capability statement, and fee schedule. The Laboratory Submission Manual includes the following (minimum) elements:

- sampling procedures for selected tests;
- packaging instructions;

- sample container and preservative requirements;
- description of chain-of-custody and sample submission forms,
- laboratory capabilities;
- quality control (QC) and quality assurance (QA) activities;
- hold times;
- turn-around times;
- laboratory contact information; and
- laboratory fees.

Handling of Test Items and Reference Materials

Test Items (Samples)

EHL maintains documented procedures that address the handling of samples (test items), including sample receipt, storage, internal chain-of-custody, security, retention, and disposal. The procedure describes the laboratory facilities and conditions required to avoid loss, deterioration or damage to samples during storage, handling, and analysis.

EHL has a system for identifying samples. The unique ID is retained throughout the life of the sample in the lab. The system is organized so as to ensure that samples cannot be confused physically or when referred to in records or other documents. The ID system accommodates a sub-division of groups of samples, and transfer of samples within and from the lab.

Reference Materials

EHL has procedures for safe handling, transport, storage, and use of standards and reference materials in order to prevent contamination or deterioration. EHL personnel do not use purchased equipment or consumable materials, including standards, reference materials, and reagents, until they have been verified to meet all agency requirements. The verification is recorded and the records are maintained.

Sample Receipt

Upon the receipt of the sample at the EHL facility, EHL personnel record abnormalities or departures from normal or specified conditions, as described in the test method. When there is doubt as to the suitability of a sample, or when a sample does not conform to the description provided, or the test required is not provided in sufficient detail, the laboratory consults the client for further instructions before proceeding, and records the discussion.

EHL has procedures and appropriate facilities for avoiding deterioration, loss or damage to samples during storage, handling, and preparation. Handling instructions provided in the appropriate procedure or provided with the sample are followed. When samples have to be stored or conditioned under specific environmental conditions, these conditions are maintained, monitored, and recorded.

Where a sample is to be held secure, the laboratory has arrangements for storage and security that protect the condition and integrity of the secured samples or sample portions concerned.

Quality Control

Test methods and procedures address all specific quality control requirements for replicate testing, spikes, blanks, retests or samples, and correlation of results for different characteristics. Quality checks are completed at defined intervals, both prior to and during the test, depending on the test method, to maintain confidence in reference, primary, transfer, or working standards and reference materials.

EHL has procedures for safe handling, transport, storage, and use of standards and reference materials in order to prevent contamination or deterioration. Laboratory personnel use method-specific quality control checks when performing technical testing procedures for monitoring the validity of tests undertaken. This monitoring shall be planned and reviewed, and may include, but not be limited to, the following:

- Certified reference materials and/or internal quality control using secondary reference standards, including negative controls (method blanks) and laboratory control samples (spikes),
- Microbiological positive and negative controls,
- Duplicates or replicate tests using the same or different methods,
- Single blind QC samples and third party performance check samples.

The data are recorded in such a way that trends are detectable. Where feasible, Quality Control Standards are traceable to international standards or vendor calibration certificates. Where appropriate, the laboratory uses Statistical Quality Control (SQC) to monitor the consistency and accuracy of testing procedures. The Quality Assurance Manager monitors trends, evaluates SQC data, and establishes internal Quality Control limits, where appropriate. The quality control check data are analyzed and, where they are found to be outside pre-defined criteria, planned actions are taken to resolve the problem or anomaly.

Intentional deviation from test methods occur only if the deviation has been documented, technically justified, and authorized. The The client is notified, and client acceptance is sought when appropriate. Unintentional deviations are documented as nonconformances.

Results Review

The laboratory uses a multi-level review process to ensure the quality of final results submitted to the client. Analytical results are reviewed for compliance with SOP requirements, data entry accuracy, report format, and client requirements. Analytical results are not released without review by at least two separate persons (analyst and 2nd level review by a supervisor or peer). This review process is described in detail in the Quality Process (QP)-18 Results Review.

Reporting Results

EHL maintains a documented procedure that addresses the content and format of test reports. The content of test reports is program dependent and varies significantly between the various programs supported by EHL. The test reports may be reported as hard copy or by electronic data transfer providing the requirements of ISO 17025:2005 are met. Results are accurately, clearly, unambiguously and objectively reported, and reported in accordance with any specific instructions in the test method. A case narrative, comments and/or footnotes about the conditions of the samples on receipt that may have affected the quality of the test results, unambiguous identification of the sample(s) tested, and interpretation of results are included.

Each test report shall include at least the following information as appropriate: title, name and address of the laboratory where the tests were carried out, a unique identification of the report along with sequential page numbers identifying each page as a part of the total test report with a clear indication of the end of the report, name and address of the client, identification of the method used, date of receipt of the sample if critical to the validity and application of the results, date of analysis, test results with appropriate unit of measure, the name/position/signature of person authorizing the test report, and any additional items relevant to the interpretation of test results.

Results from tests performed by subcontracted laboratories are identified as such.

Material amendments to a test report after issue are made only in the form of a further document or version, which shall be identified as a "Supplement to Test Report" and refers to the original unique report number. Such amendments or versions meet all the requirements of the EHL QMS. When it is necessary to issue a completely new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

Supporting Documents

ISO 17025:2005, clauses 5.4, 5.7, 5.9, and 5.10.
Quality Procedure: QP-04: Contract Requisition Review and Authorization.
Quality Procedure: QP-13 Personnel Qualifications and Training
Quality Procedure: QP-14 Measurement Uncertainty
Quality Procedure: QP-15 Data Protection and Security
Quality Procedure: QP-17 In-House Validation of Methods
Quality Procedure: QP-18 Results Review
Quality Procedure: QP-19 Sample Receipt
Quality Procedure: QP-20 Quality Control
Quality Procedure: QP-21 Reporting Test Results
Laboratory Submission Manual
http://www.dec.alaska.gov/eh/docs/lab/Lab%20Sample%20Submission%20Manual.pdf

QSE Policy: Documents and Records

Policy

All instructions, standard methods, manuals, and reference data relevant to the work of the EHL shall be kept up to date and readily available to personnel. EHL maintains documented procedures to identify and control documents, both hardcopy and electronic, that relate to the QMS. These include documents of external origin.

EHL maintains a documented procedure that addresses the control of all technical records and records relating to conformance with, and the effective operation of its QMS.

Document Control

EHL maintains instructions on testing operations, on the use and operation of all relevant equipment, and on the handling and preparation of items for testing, where the absence of such instructions could jeopardize the results of tests.

Authorized personnel review and approve controlled documents for accuracy before issue. A master list identifies the current revision status of documents and precludes the use of invalid or obsolete documents.

An individual from the same function that peer reviewed the original document reviews and makes changes unless specifically designated otherwise. An individual from the same function that approved the original document approves changes unless specifically designated otherwise. The revised document specifies the nature of the changes associated with its revision.

QMS documents are controlled and accessible electronically wherever essential operations are performed. Staff may only use hard copies if the user can verify the correct revision with the master list. Documents not maintained electronically, such as documents of external origin, are legible and stored for accessibility in a suitable environment to prevent damage, deterioration, or loss. The Quality Systems Manager (QSM) handles obsolete documents according to the documented procedure.

Control of Records

Record control provides for the:

- identification, collection, indexing, filing, storage, maintenance, retrieval, retention time, and disposition of quality records;
- correction of records, when necessary;
- security of records;
- backup and protection of electronic records;
- access to electronic records; and
- protection of the customers' confidential information and proprietary rights.

Quality records are legible, readily identifiable, and stored for accessibility in a suitable environment to prevent damage, deterioration or loss. Control of quality records includes both electronic and hard copy media.

All observations, data, and calculations are recorded at the time they are made and are identifiable to the specific task.

When mistakes occur in hard-copy records, each mistake is crossed or lined out with a single line, and not erased, made illegible or deleted. The correct value is then entered alongside. All such alterations to records are signed or initialed by the person making the correction, with the date of the correction. In the case of records stored electronically, an audit trail is used to avoid loss or change of original data.

All records pertaining to analytical equipment and analytical reports are safely stored, and held secure and in confidence to the client.

EHL retains on record all original observations, calculations, derived data, calibration records, and a copy of the test report(s). EHL quality records include the identity of personnel involved in analysis of the samples, and review of the results. Analytical reports include the identification of the analytical method to permit verification by analytical repetition.

Where possible, the records for each test contain sufficient information to reconstruct the original reported result and uncertainty. The records are retained for at least five years.

Reporting Results and Amendments to Records and Reports

EHL notifies the client in writing of any typographical error(s) or of any defective test equipment that casts doubt on the validity of results stated in the report.

The EHL amends or corrects test reports after issue in a manner as to refer to the original report it replaces.

Staff are not authorized to give opinions concerning the meaning of client results.

Supporting Documents

Quality Procedure: QP-03 Document Control
Quality Procedure: QP-10 Control of Records

QSE Policy: Information Management

Policy

The Analyst/Programmer and Technical Manager, in conjunction with State of Alaska IT Department resources, provides for the maintenance of EHL computer resources and automated equipment, respectively, to ensure proper functioning. The Maintenance Specialist ensures that environmental and operating conditions within the laboratory facility comply with manufacturer recommendations, relayed by the Technical Manager(s), to protect the integrity of analytical data.

Data Security

EHL maintains a documented procedure that addresses data security, including data integrity, confidentiality, storage, transmission and processing, and the prevention of unauthorized access to, or the unauthorized amendment of computer records. The procedure ensures the protection of EHL client confidentiality, information, and proprietary rights in accordance with State of Alaska policies and statutes.

EHL backs up all electronic data in appropriate formats according to documented procedures.

EHL maintains a documented procedure for maintaining accessibility of data created by older/obsolete hardware/software systems/applications, according to applicable records retention policies.

EHL personnel follow documented procedures in accordance with the quality system for any transmission of test results via email, internet, facsimile, or other electronic or electromagnetic means.

Computer Downtime

The EHL maintains a procedure for laboratory operations when the Laboratory Information System is not functioning.

Supporting Documents

Quality Procedure: QP-01 Client Confidentiality
Quality Procedure: QP-15 Data Protection and Security
Quality Procedure: QP-21 Reporting Test Results
Quality Procedure: QP-26 Computer Operations During Downtime

QSE Policy: Occurrence Management

Policy

EHL maintains a documented procedure that addresses the activities implemented whenever any testing activity, or the results of such activity, does not conform to EHL procedures or testing requirements.

Records are maintained of all investigations and corrective actions taken by the laboratory.

Control of Non-conforming Tests

The procedure for control of non-conforming tests:

- defines non-conforming tests;
- designates responsibilities and authorities for managing nonconforming work;
- specifies possible actions taken when nonconforming work is identified;
- requires an investigation to determine why work is nonconforming;
- provides for the evaluation of the significance of the nonconforming work;
- indicates that corrective actions are required immediately;
- requires a decision regarding the acceptability of the nonconforming work;
- addresses client or other appropriate notification activities;
- indicates how nonconforming work is to be recalled if appropriate; and
- defines the responsibilities for authorizing the resumption of work.

Client Notification

EHL notifies the client in writing of any typographical error or any defective measuring or test equipment that casts doubt on the validity of the results stated in the report.

Supporting Documents

Quality Procedure: QP-09 Non-conformance, Corrective action, and Preventive action

QSE Policy: Assessments

Policy

EHL maintains a program for internal assessments of its quality management system and operations, and participates in external assessments such as proficiency testing and regulatory and accreditation inspections. These programs help verify that EHL operations continue to comply with quality system requirements and requirements of applicable standards and regulations.

Internal Assessing

EHL assesses all areas of the management systems at least once every three years. The Quality Systems Manager (QSM) is responsible for planning assessments. Unscheduled assessments may take place if the QSM identifies a need. EHL uses trained, in-house personnel independent of the activity to be assessed (whenever resources permit) or qualified third parties to conduct internal assessments.

EHL maintains a documented procedure that addresses internal assessment criteria and scope, frequency and methodologies, responsibilities, and requirements for personnel conducting the assessments.

When internal assessment findings cast doubt on the effectiveness of the operations or on the correctness or validity of EHL test results, the lab takes corrective action in a timely manner.

The QSM is responsible for tracking corrective actions necessary to satisfy deficiencies found during the assessment. The corrective actions are documentedin the same manner as nonconformances.

The QSM monitors follow-up actions to verify and record the implementation and effectiveness of the corrective actions taken.

External assessments

EHL participates in the periodic external inspections and assessments that are required to maintain its accreditation or certification status.

The laboratory participates in the triennial onsite laboratory evaluation programs conducted by federal officers, to include EPA SDWA laboratory certification officers, FDA laboratory evaluation officers, or FDA certified state laboratory evaluation officers.

The laboratory participates in ongoing inspections, assessments, and performance evaluation sample analysis sponsored by various agencies, including but not limited to:

- USDA-APHIS (Approval for EIA, Brucellosis analysis)
- FDA (Dairy, Shellfish)

- EPA (Drinking water)
- OSHA

When external assessment findings cast doubt on the effectiveness of the operations or on the correctness or validity of EHL test results, the lab takes corrective action within the deadlines set by the certifying agency.

Proficiency Testing

The laboratory participates in annual proficiency test programs appropriate for its testing capabilities. Examples include, but are not limited to, FDA-sponsored splits testing, and Water Supply Proficiency Testing required by the EPA Safe Drinking Water Program.

Records

The QSM maintains records of internal assessments, including follow-up actions to correct identified deficiencies.

The QSM maintains records of external inspections and assessments, and the follow-up actions to correct identified deficiencies.

Management Review

Results of internal assessments and external assessments are provided for management review. Management reviews internal and external assessment results at each management review meeting.

EHL management ensures that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

Supporting Documents

Quality Procedure: QP-11 Internal Assessing

QSE Policy: Process Improvement

Policy

EHL maintains documented procedures for corrective action and preventive action.

Corrective Action

Corrective actions are initiated as a result of:

- client complaints and feedback;
- nonconformance reports;
- management review;
- internal audits;
- output from data analysis;
- review of QMS records;
- output from satisfaction surveys;
- employee-identified process problems;
- deficiencies identified from external assessments and inspections; and
- the potential for nonconforming work to recur.

The EHL procedure for corrective action addresses;

- the effective handling of client complaints and reports of service nonconformity;
- the investigation of the root cause of nonconformity relating to the service; process and QMS, and recording the results of the investigation;
- assignment of appropriate authorities for implementing corrective action;
- determination of the corrective action needed to most likely eliminate the cause of the nonconformity;
- ensuring that corrective action is taken and that it is effective;
- containment actions aimed at reducing or eliminating similar nonconformance events;
- recording of corrective action taken;
- monitoring and recording the results of actions taken;
- reviewing the corrective action taken; and
- determining the necessity for additional auditing of the nonconforming area.

Corrective actions are implemented that are appropriate to the magnitude of the problems discovered.

Preventive Action

Preventive actions may be initiated from any of the following:

- review of client needs and expectations;
- market analysis;
- management review output;
- output from data analysis;
- customer and employee satisfaction measurements;

- lessons learned from past experiences; and
- changes in management or employee expectations, goals, and objectives.

The EHL procedure for preventive action addresses:

- the use of sources of information to detect, evaluate, and eliminate potential causes of nonconformities;
- investigation of the causes of potential nonconformities of service processes and the QMS, and recording the results;
- determination of the steps needed to deal with any problems requiring preventive action;
- initiatiing preventive actions and ensuring that they are effective; and
- submittal of relevant information on actions taken for management review.

Supporting Documents

Quality Procedure: QP-09 Non-conformance, Corrective Action, and Preventive Action